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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,307	10/26/2001	Michael R.S. Hill	P-8969.00	2140
27581	7590	05/13/2008		
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924			EXAMINER OROPEZA, FRANCES P	
			ART UNIT	PAPER NUMBER
			3766	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/039,307	Applicant(s) HILL ET AL.	
	Examiner FRANCES P. OROPEZA	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/14/08 (Amendment).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response

1. The Applicant amended claim 19 in the response file 2/14/08, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 112

2. Claim 22 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner is unable to find a teaching of the lead arrangement and the methodology for triple chamber cardiac resynchronization therapy in the original specification, hence this limitation is deemed to be new matter. New matter may not be entered at this point in the prosecution. Appropriate correction is required.

The Applicant indicated support for the amendment of claim 22 on 6/26/07 was found on at page 11, lines 20 to 23 and page 12 lines 1-4 of the filed application. The Examiner found the citations on page 8, lines 9-13 of the specification filed 10/26/01. The citations do not specify the resynchronization therapy is applied as “triple chamber” resynchronization therapy, hence the rejection of record stands.

Claim Rejections - 35 USC § 103

3. Claims 17, 18, 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US 5199428) and Collins (US 5203326) in view of Limousin (FR 2 805 469 – A1 / English translation in equivalent U.S Patent No. 6,937,898).

Obel et al. disclose an implantable electrical nerve stimulator/ pacemaker for a human/ mammal, the nerves being automatically stimulated in the region of the thoracic vertebra T2 providing electrical communication and the stimulation coordinated to resynchronization the heart to protect the myocardium (abstract; col. 1 @ 15-24; col. 3 @ 8-28 & 42-45; col. 3 @ 62 – col. 4 @ 26; col. 5 @ 25-64).

Obel et al. disclose pacing therapy using a anti-tachycardia pacing system (col. 9 @ 53 – col. 10 @ 2) and therapy using a back-up pacemaker (104) (col. 6 @ 66 – col. 7 @ 25) that can also provide programmable parameters and alternate pacing modes (col. 8 @ 49-62).

Obel et al. teach cardiac therapy that decreases cardiac workload (abstract), protects the myocardial cells by reducing the oxygen demand, hence optimizing cardiac output (col. 2 @ 9-13), decreases the ischemia and the potentially induced arrhythmias such as brady-arrhythmia and tachycardia (col. 2 @ 59-65, col. 3 @ 29-33, col. 9 @ 53-57), provides pacing therapies to maintain the patient's heart rhythm within acceptable limits (col. 3 @ 8-13), ameliorates myocardial ischemia and maintains adequate cardiac rate (col. 3 @ 14-15), exerts a tonic effect to slow the heart down and control tachycardia (col. 5 @ 5-18), and treats conditions and arrhythmias of a heart associated with coronary artery disease and myocardial insufficiency (col. 10 @ 31-35), these therapy outcomes read to improve cardiac performance and efficiency of the patient's heart.

As to claim 22 and improving the balance of a neuro-endocrinological system, it is well known in the art as disclosed in US 5203326 to Collins (cited as art made of record) that:

- electrical stimulation of the nerves of the autonomic nervous system can be used to the control the heart (abstract),
- the autonomic nervous system includes the sympathetic and the parasympathetic nervous systems that regulate activities of the cardiac muscle (heart) and the glands (endocrine system) (col. 1 @ 36-39), and
- the autonomic nervous system can be stimulated by the vagal nerve to treat arrhythmias (col. 5 @ 5-40; col. 5 @ 59 – col. 6 @ 35).

hence, Obel et al. is accepted to teach improving of the neuro-endocrinological system.

It is noted the concepts of treating a patient to improve cardiac performance and efficiency of the patient's heart, and to improve balance of a neurological system of the patient amount to an intended use limitations of which Obel et al. performs or is inherently capable of performing.

As discussed in the previous six paragraphs of this action, Obel et al. disclose the claimed invention except for the pacing therapy being cardiac resynchronization therapy.

Limousin teaches anti-tachycardia pacing therapy using cardiac resynchronization therapy for the purpose of treating and managing ventricular tachycardia. Three chambers, two ventricles and an atria, triple chambers, are accepted to be included in this therapy. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used cardiac resynchronization therapy in the Obel et al. system in order to provide a pacing therapy mode that is more effective in terminating organized ventricular tachycardia condition than

Art Unit: 3766

previously known anti-tachycardia pacing therapies, the invention recognizing that shock therapy can be used if the resynchronization therapy is not successful to terminate the tachycardia condition (abstract; figure 1; col. 1 @ 11-10, 45-50; col. 2 @ 12-21; col. 2 @ 25 – col. 3 @ 2; col. 4 @ 1-15).

The Applicant arguments filed 2/14/08 have been fully considered, but they are not convincing.

In response to the Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Obel et al. teach pacing therapy and neural electrical stimulation to decrease the cardiac work load, optimize the cardiac cycle and cardiac output, and treat arrhythmias (abstract; col. 5 @ 12-16). Collins teaches autonomic nervous system stimulation to provide therapy for abnormal heart conditions such as arrhythmias (abstract; col. 6 @ 1-35). Limousin teaches cardiac resynchronization therapy to manage arrhythmias such as ventricular tachycardia (abstract). The combination of the three references is deemed appropriate and is deemed to teach the instant invention. The rejection of record stands.

4. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US 5199428) and Collins (US 5203326) and Limousin ((FR 2 805 469 – A1 / English translation in equivalent U.S Patent No. 6,937,898) in view of Adams (US 57992187).

As discussed in paragraph 3 of this action, modified Obel et al. disclose the claimed invention except the electrode located external to the patient's body against the skin.

Adams teaches pain suppression treatment using an electrode (100) located external to the patient's body on the skin at the spine proximate to the dorsal root sensory ganglia for the purpose of relieving pain associated with the high voltage stimulation. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an electrode located external to the patient's body in the modified Obel et al. system in order to offer a proven treatment for the pain associated with high voltage shocks so the patient's pain, apprehension, and anxiety is controlled (abstract; figures 4; col. 2 @ 48-55; col. 3 @ 1-8, 45-48; col. 7 @ 11-24). It is noted both electrical and electromagnetic pain suppression systems are well know in the art, and absent any teaching of criticality or unexpected results merely changing the type of system from an electromagnetic system to an electrical system would be an obvious design choice.

The Examiner finds the Applicant's arguments filed 2/14/08 and related to the rejection of claim 19 are unclear, making it difficult to respond. The Examiner does not "suggests that the claimed subject matter is not directed this subject matter". The Examiner is unclear about what "foregoing" is referring to in the second full sentence on page 8 of the Applicant's response.

The Applicant asserts Adams does not teach the subject matter claimed in claim 19. The Examiner disagrees. Adams teaches electrode stimulation located external to the patient's body on the skin. The combination of the references has been reviewed and is deemed appropriate, hence the rejection of record stands

Specification

5. The amendment filed 6/26/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In claim 22, the limitation "a triple chamber" cardiac resynchronization therapy.

Applicant is required to cancel the new matter in the reply to this Office Action.

Statutory Basis

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. Fran's schedule typically is Monday and Tuesday 9AM-7PM EST. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's Supervisor, Carl. H. Layno can be reached on (571) 272-4949. Carl's schedule typically is Monday, Wednesday, Friday 9AM-5 PM EST; Tuesday, Thursday 9AM-3PM and 9PM-11PM EST. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

Art Unit: 3766

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Frances P. Oropeza/

Patent Examiner, Art Unit 3766

/Carl H. Layno/

Supervisory Patent Examiner, Art Unit 3766